MISSISSIPPI LEGISLATURE REGULAR SESSION 2020

By: Representative Currie

To: Public Health and Human Services

HOUSE BILL NO. 829

AN ACT TO DIRECT THE STATE DEPARTMENT OF HEALTH TO DEVELOP AND IMPLEMENT A STATE-ADMINISTERED WHOLESALE PRESCRIPTION DRUG IMPORTATION PROGRAM THAT IS SAFE FOR MISSISSIPPI CONSUMERS AND GENERATES SUBSTANTIAL SAVINGS FOR MISSISSIPPI CONSUMERS; TO PROVIDE THAT UNDER THE PROGRAM, THE STATE OF MISSISSIPPI WILL BE THE LICENSED WHOLESALER, IMPORTING DRUGS FROM A LICENSED, REGULATED CANADIAN SUPPLIER, SOLELY FOR DISTRIBUTION TO VOLUNTARILY PARTICIPATING, STATE-LICENSED, IN-STATE, PHARMACIES AND ADMINISTERING PROVIDERS FOR THE EXCLUSIVE PURPOSE OF DISPENSING TO STATE RESIDENTS WITH A VALID PRESCRIPTION; TO SPECIFY THE ISSUES THAT THE DEPARTMENT MUST ADDRESS IN DEVELOPING THE PROGRAM FOR FEDERAL CERTIFICATION; TO PROVIDE THAT THE DEPARTMENT WILL SUBMIT A FORMAL REQUEST TO THE SECRETARY OF THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES FOR CERTIFICATION OF THE PROGRAM AND BEGIN IMPLEMENTATION OF THE PROGRAM AND HAVE THE PROGRAM OPERATIONAL WITHIN SIX MONTHS AFTER THE DATE OF THE SECRETARY'S CERTIFICATION; TO PROVIDE THAT THE DEPARTMENT SHALL MAKE REGULAR REPORTS TO LEGISLATIVE COMMITTEES ON THE DEVELOPMENT AND IMPLENTATION OF THE PROGRAM; AND FOR RELATED PURPOSES.

WHEREAS, United States citizens pay some of the very highest prices for prescription drugs in the world and the Canadian government estimated that United States consumers pay twice as much as Canadians for patented prescription drugs and 20 percent more for generic drugs; and

WHEREAS, under FDA discretion not to enforce the law, individual patients may import a 90-day supply of prescription

drugs from Canada that are less expensive than drugs licensed by the FDA in the United States; and

WHEREAS, individual importation via the Internet increases consumer health and safety risks because many Internet pharmacies are not licensed in Canada and it is difficult to verify the validity, reputation, actual identity and pharmacy practices of ex-United States, on-line pharmacies; and

WHEREAS, the United States allows patients to go to other countries for surgeries and other high-risk medical treatments without regulating that consumer purchasing activity and insurers sometimes facilitate and pay for ex-United States treatments; and

WHEREAS, the FDA estimates that currently 40 percent of finished prescription drug products are produced outside the United States and 80 percent of the raw product for United States pharmaceutical manufacturing comes from outside the United States; and

WHEREAS, the FDA has signed reciprocity agreements with European Union regulators to accept the results of EU inspections pharmaceutical manufacturing plants, and the FDA has had a Memorandum of Understanding for regulatory cooperation around pharmaceuticals with the Canadian regulatory authorities since 1973; and

WHEREAS, Canada has a rigorous regulatory system to license prescription drugs that is considered to be on par with the United States licensing system;

WHEREAS, Title II of the federal Drug Quality and Security Act (P.L. 113-54), Drug Supply Chain Security, has resulted in improvements in drug security and safety through a system of pharmaceutical track and trace that can be leveraged for safe importation; and

WHEREAS, the Secretary of the United States Department of Health and Human Services may certify a prescription drug reimportation program that is safe and saves consumers money; and

WHEREAS, the State of Mississippi can assure that wholesale importation of prescription drugs from Canada into our state will be safe and cost-saving for Mississippi consumers; NOW THEREFORE,

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MISSISSIPPI:

SECTION 1. (1) The State Department of Health shall develop and implement a state-administered wholesale prescription drug importation program that is safe for Mississippi consumers and generates substantial savings for Mississippi consumers.

(2) Under the program, the State of Mississippi will be the licensed wholesaler, importing drugs from a licensed, regulated Canadian supplier, solely for distribution to voluntarily participating, state-licensed, in-state, pharmacies and administering providers for the exclusive purpose of dispensing to state residents with a valid prescription.

SECTION 2. In developing the program, the department shall consult with relevant state stakeholders and federal offices and agencies that will meet relevant requirements of 21 USC Section

384, including safety and cost savings. In developing the program for federal certification, the department shall address the following issues:

(a) That a state agency becomes a licensed wholesaler for the purpose of seeking federal certification and approval to import safe prescription drugs that will provide savings to Mississippi consumers;

(b) That the program uses Canadian suppliers regulated under the appropriate Canadian and/or provincial laws;

(c) That the program has a process to sample the purity, chemical composition, and potency of imported products;

(d) That the program only imports those prescription pharmaceuticals expected to generate substantial savings for Mississippi consumers;

(e) That the program ensures that imported products will not be distributed, dispensed, or sold outside of Mississippi borders;

(f) That the program ensures that voluntary participant, state-licensed, pharmacies and administering providers charge individual consumers and health plans the actual acquisition cost of the imported, dispensed product;

(g) That the program ensures that health plan payment of the product component of pharmacy and provider billing reimburses no more than the actual acquisition cost of the dispensed, imported product;

(h) That the program ensures that participating health plans keep their formularies and claims payment systems up to date with the prescription drugs provided through the wholesale importation program;

(i) That the program ensures that participating health plans base patient cost sharing on no more than the actual acquisition cost of the dispensed, imported product;

(j) That the program requires participating health plans to demonstrate to the department how savings on imported drugs are reflected in premiums;

(k) That profit margin of any participating wholesaler and/or distributor(s) of imported pharmaceutical products is limited to a specified amount established by the department;

(l) That the program does not import generic products that would violate United States patent laws on United States branded products;

(m) That the program complies with the requirements of 21 USC Sections 360eee through 360eee-4, pertaining to the track and trace requirements as enacted in Title II of the Drug Security and Quality Act (Public Law 113-54), Drug Supply Chain Security, to the extent practical and feasible before imported drugs come into possession of the state wholesaler and complies fully after imported drugs are in the possession of the state wholesaler;

(n) That the program is adequately financed through a fee on each prescription or other appropriate approach, but the size of the fee cannot jeopardize significant consumer savings;

(o) That the program includes an audit function to ensure that:

(i) The department has a sound methodology by which to determine the most cost effective products to include in the importation program on an ongoing basis;

(ii) The department has processes in place to select Canadian suppliers of high quality, high performance, and in full compliance with Canadian law and regulations and state pharmacy wholesaler laws;

(iii) Imported drugs under the program are not shipped, sold, or dispensed outside the state once in the possession of the state;

(iv) Imported products are pure, unadulterated, potent, and safe;

(v) Participating pharmacies and administering providers are not charging more than actual acquisition cost to any consumer or any participating health plan;

(vi) Participating health plan formularies and claims processing systems remain up to date with all relevant aspects of the importation program;

(vii) Participating health plans base patient coinsurance and other cost sharing on the actual acquisition cost of covered, imported drugs;

(viii) Participating health plans reimburse participating pharmacies and administering providers actual acquisition cost for imported, dispensed products;

(ix) The program is adequately financed to support all administrative functions while generating significant consumer savings;

(x) The program does not put consumers at higher risk than if the program did not exist; and

(xi) The program continues to provide Mississippi consumers with substantial savings on prescription drugs.

SECTION 3. The department shall enlist the assistance of the Attorney General to identify the potential for anticompetitive behavior in industries that would be affected by a program of wholesale importation of prescription drugs.

SECTION 4. The department shall report to the House and Senate Appropriations Committees, the House Public Health and Human Services Committee and the Senate Public Health and Welfare Committee within six (6) months after the effective date of this act on the final wholesale prescription drug importation program design that takes into consideration at least the items specified in Section 2 of this act.

SECTION 5. After review by the legislative committees specified in Section 4 of this act, the department shall submit a formal request to the Secretary of the United States Department of Health and Human Services for certification of the state's wholesale prescription drug importation program. The department shall submit the request to the Secretary within two (2) weeks after the committees have completed their review.

SECTION 6. Upon certification and approval by the Secretary of the United States Department of Health and Human Services, the department shall begin implementation of the wholesale prescription drug importation program and have the program operational within six (6) months after the date of the Secretary's certification. As part of the implementation process the department shall, in accordance with state procurement and contracting laws and rules as appropriate:

(a) Become licensed as a wholesaler;

(b) Contract with a state-licensed distributor or distributors;

(c) Contract with a licensed, regulated, Canadian supplier or suppliers;

(d) Engage health plans, employers, pharmacies, providers, and consumers;

(e) Develop a registration process for health plans, pharmacies, and administering providers willing to participate;

(f) Create a publicly available source for listing prices of imported products that will be available to all participating entities and consumers;

(g) Create an outreach and marketing plan to generate program awareness;

(h) Create and staff a hotline to answer questions from any affected sector starting in the weeks before the program becomes operational that can address the needs and questions of consumers, employers, plans, pharmacies, and providers, among others;

(i) Establish the audit function and a two (2) year audit work plan cycle; and

(j) Conduct any other activities determined to be important to successful implementation as determined by the department.

SECTION 7. The department shall report biannually to the legislative committees specified in Section 4 of this act, beginning with either the first June or December after the date of implementation, whichever is the nearest date to the date that is six (6) months after program implementation. The report to the committees shall include:

(a) The drugs covered in the wholesale importation program;

(b) The number of participating pharmacies, providers and health plans;

(c) The number of prescriptions dispensed under the program in the period;

(d) The estimated savings to consumers, health plans, and employers that resulted from the program in the reporting period and to date;

(e) In the first three (3) reporting periods, information on the implementation of the audit plan and, on an on-going basis, audit findings for the reporting period; and

(f) Any other information of importance as determined by the department.

SECTION 8. This act shall take effect and be in force from and after July 1, 2020.